

REMARKS/ARGUMENTS

In response to the Office Action of January 27, 2005, Applicant provides the following remarks, which further support patentability of the present application. Favorable consideration of all pending claims is earnestly solicited.

Claims 11-20 have been rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Hauer et al. (U.S. Patent No. 5,342,625). Hauer et al. has been cited for disclosing a pharmaceutical composition that comprises cyclosporin, oil, hydrophilic surfactant that has an HLB of greater than 10 and lipophilic surfactant having an HLB of less than 10 (column 9, lines 40-47; examples 1.6-1.10; column 12, lines 35-41) and that excess surfactants may be additional carriers and co-solvents as part of the hydrophilic or lipophilic phase (column 12, lines 42-48). See Office Action, page 2. The Examiner readily admits that while Hauer et al. discloses that sorbitan esters are equally useful as lipophilic surfactants, the reference does not disclose Applicant's specific combination of surfactants. However, the position of the Examiner is that polyglycerol esters are recognized in the art as lipophilic surfactants (column 2, lines 2-9 of Reggio et al., U.S. Patent No. 4,379,169 as a teaching reference).

According to the Examiner, one skilled in the art would have had the skills necessary to prepare pharmaceutical compositions by simple mixing of ingredients and such a mixing process would be *prima facie* obvious. Therefore, according to the Examiner, "it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and use the pharmaceutical composition of Hauer (*sic*). One having ordinary skill in the art would have been motivated to combine lipophilic and hydrophilic with the expectation of rendering the cyclosporins soluble. Selection of the surfactants from among equally suitable material is proper and obvious, see *Ex parte Winters*, 11 USPQ2d 1387." See *Office Action*, Page 3.

Applicant respectfully traverses the rejection. The Examiner readily admits that Hauer et al. does not disclose the specific combination of surfactants used in the compositions of the presently claimed invention. See January 27, 2005 Office Action, page 2, last paragraph. Applicant respectfully submits that the specific combination of surfactants presently claimed, is also nowhere suggested in Hauer et al. It is the Examiner's position that polyglycerol esters are recognized in the art as lipophilic surfactants, and directs Applicant to column 2, lines 2-9 of Reggio et al., U.S. Patent No. 4,379,169, as a teaching reference. Applicant does not agree that Reggio et al. reflects that polyglycerol esters are recognized in the art as lipophilic surfactants. The passage referred to by the Examiner when put in the context of the preceding paragraphs, indicates that polyglycerol esters may be used as a unique plasticizing agent in a chewing gum base in order to confer superior film-forming properties and thus superior bubble-blowing character. Nowhere in Reggio et al. are polyglycerol esters ever referred to as lipophilic surfactants. It is respectfully submitted that polyglycerol esters as plasticizing agents for use in a chewing gum base, is a non-analogous art to the present invention, a pharmaceutical composition comprising a solubilized therapeutic agent which is sparingly soluble in water and a carrier composition.

The rejection of claimed subject matter under 35 U.S.C. § 103 requires that both the suggestion to carry out the invention and a reasonable expectation of success must be found in the prior art, not in Applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 492, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991). A suggestion to make the presently claimed invention and a reasonable expectation of success is not found anywhere in Hauer et al. In particular, a suggestion to make the pharmaceutical compositions of the present invention and a reasonable expectation of success in obtaining the same, in which cyclosporin (and other therapeutic agents such as rapamycin, tacrolimus, deoxyspergualine, mycophenolate-mofetil, nifedipine, nimodipine, toproside or ibuprofen) are contained in a carrier medium comprising a sorbitan fatty acid ester having an HLB value of less than 10, an oil comprising a triglyceride as essential lipophilic component, and a nonionic surfactant having an HLB value of greater


than 10, in the relative amounts presently claimed, is simply nowhere to be found in Hauer et al.

Even if the Examiner is correct that Hauer et al. suggests that one skilled in the art should combine hydrophilic with lipophilic phases in order to render cyclosporin soluble, and select a surfactant from among equally suitable materials (a point on which Applicant does not agree with the Examiner), at most, such suggestion can only be taken as an invitation to experiment, i.e., an "obvious to try" situation. "Obvious to try" however, is not the standard under 35 U.S.C. § 103(a). *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Withdrawal of the rejection of claims 11-20 under 35 U.S.C. § 103(a) is therefore warranted.

In view of the foregoing remarks, it is firmly believed that the subject case is in condition for allowance, which action is earnestly solicited.

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Respectfully submitted,



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